

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Sep 2026

### Effectiveness of the Cognitive behavioral therapy(CBT) in improving nutritional and weight status in overweight adolescents

#### Protocol summary

##### Study aim

The purpose of this study is to examine the effectiveness of cognitive behavioral therapy (CBT) on weight loss in obese and overweight adolescents

##### Design

The present study is a prospective randomized controlled trial (RCT) comparing the effect of CBT on weight reduction among overweight and obese Iranian adolescents.

##### Settings and conduct

The adolescents will be recruited from four outpatient pediatric clinics in Qazvin .

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age 13-18 years, BMI  $\geq$ 85th percentile for age and gender, and ability to attend CBT sessions.

Exclusion criteria : adolescents with other causes of obesity such as Cushing Disease and hypoparathyroidism, being pregnant, having clinical mental health conditions or psychosis, taking specific medications that affected their weight (e.g. corticosteroids, anxiolytics), and participating in another weight loss RCT.

##### Intervention groups

CBT treatment sessions will be based on treatment strategies in the intervention group comprised six face-to-face sessions for adolescents and two sessions for their parents. In all sessions, nutritional recommendations and diet of the adolescents will be evaluated.

##### Main outcome variables

Primary outcomes will be changes in BMI, Child Dietary Self-Efficacy Scale (CDSS), Weight Efficacy Lifestyle questionnaire (WEL), Physical Exercise Self-Efficacy Scale (PES), Pediatric Quality of Life Inventory (PedsQL™ 4.0 Generic Core Scales), and self-reported physical activity and diet

#### General information

##### Reason for update

We had been registered this trial 6 years before prospectively. But it has recently changed unto a retrospective status. We received the following message from IRCT " Please note that the existing validation errors in your trial is because this trial has been approved while the previous version of IRCT software was in use. Please check all the errors carefully and update accordingly. some of the major changes include reformatting protocol summary, entering inclusion and exclusion criteria in "one phrase for each criteria" format, providing a sharing plan, and adding more contact information." Therefore, we have now updated recruiting time.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016110530707N1**

Registration date: **2017-01-22, 1395/11/03**

Registration timing: **prospective**

Last update: **2023-06-13, 1402/03/23**

Update count: **1**

##### Registration date

2017-01-22, 1395/11/03

##### Registrant information

##### Name

Seyedeh Fatemeh Miri

##### Name of organization / entity

Qazvin Medical Science University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3333 6001

##### Email address

f.miri@qums.ac.ir

##### Recruitment status

**Recruitment complete**

**Funding source**

Investigator

**Expected recruitment start date**

2017-02-03, 1395/11/15

**Expected recruitment end date**

2017-06-15, 1396/03/25

**Actual recruitment start date**

2017-02-03, 1395/11/15

**Actual recruitment end date**

2017-08-12, 1396/05/21

**Trial completion date**

2018-03-06, 1396/12/15

**Scientific title**

Effectiveness of the Cognitive behavioral therapy(CBT) in improving nutritional and weight status in overweight adolescents

**Public title**

Effectiveness of the Cognitive behavioral therapy(CBT) in improving nutritional and weight status in overweight adolescents

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

age 13-18 years BMI  $\geq$ 85th percentile for age and gender ability to attend CBT sessions

**Exclusion criteria:**

Cushing Disease hypoparathyroidism being pregnant having clinical mental health conditions or psychosis, taking specific medications that affected their weight participating in another weight loss RCT

**Age**

From **13 years** old to **18 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **110**

Actual sample size reached: **110**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Each adolescent will be recruited at the pediatric clinic to which they referred for treatment. Randomization will be performed after checking eligibility criteria, signing of informed consent, and baseline assessment. An independent biostatistician will randomize the adolescents into two groups (CBT and TAU) using software program and stratifying with the pediatric clinics.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Qazvin Medical Science University Ethics committee

**Street address**

Medical Science University, Shahid Bahonar Blvd

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3419759811

**Approval date**

2016-10-19, 1395/07/28

**Ethics committee reference number**

IR.QUMS.REC.1395.172

**Health conditions studied****1****Description of health condition studied**

overweight or obesity

**ICD-10 code**

E65, E66,

**ICD-10 code description**

Obesity and other hyperalimentation / Obesity due to excess calories

**Primary outcomes****1****Description**

weight

**Timepoint**

before intervention and after 6 month

**Method of measurement**

balance scale

**Secondary outcomes****1****Description**

body mass index

**Timepoint**

before and after intervention

**Method of measurement**

weigh(kg)/(height)2

## 2

### **Description**

waist circumference

### **Timepoint**

baseline and 6 month after intervention

### **Method of measurement**

meter

## 3

### **Description**

hip circumference

### **Timepoint**

at baseline and 6 month after intervention

### **Method of measurement**

meter

## 4

### **Description**

energy intake

### **Timepoint**

at baseline and 6 month after intervention

### **Method of measurement**

food frequency questionnair

## 5

### **Description**

physical activity

### **Timepoint**

at baseline and 6 month after intervention

### **Method of measurement**

physical activity questionnair

## 6

### **Description**

health-related quality of life

### **Timepoint**

at baseline and 6 month after intervention

### **Method of measurement**

quality of life questionnaire

## 7

### **Description**

self efficacy

### **Timepoint**

at baseline and 6 month after intervention

### **Method of measurement**

questionnaire

## 8

### **Description**

body composition

### **Timepoint**

at baseline and 6 month after intervention

### **Method of measurement**

body analyser

## **Intervention groups**

### 1

#### **Description**

Intervention group: Cognitive behavioral therapy (CBT) will be used in this study. Intervention group will receive CBT consisted of six weekly, face to face sessions.

#### **Category**

Behavior

### 2

#### **Description**

Control group: This group will not receive any treatment during the study. they will receive counseling sessions at the end of study similar to intervention group.

#### **Category**

N/A

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

outpatient pediatric clinics

##### **Full name of responsible person**

Seyedeh Fatemeh Miri

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Medical Science University, Shahid Bahonar Blvd

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f.miri@qums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Qazvin University of Medical Sciences

##### **Full name of responsible person**

Vice chancellor for research, Qazvin Medical Science University

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Sdh@qums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Qazvin University of Medical Sciences

**Proportion provided by this source**  
100

**Public or private sector**  
Public

**Domestic or foreign origin**  
Domestic

**Category of foreign source of funding**  
empty

**Country of origin**

**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Qazvin Medical Science University

**Full name of responsible person**  
Seyedeh Fatemeh Miri

**Position**  
MSc student

**Latest degree**  
Master

**Other areas of specialty/work**  
Nutrition

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Qazvin University of Medical Sciences

**Full name of responsible person**  
Amir H Pakpour

**Position**  
PhD, Health education

**Latest degree**  
Ph.D.

**Other areas of specialty/work**

Health Promotion

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Qazvin University of Medical Sciences, Shahid Bahooonar Blvd, Social Determinants of Health Research Center

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## Person responsible for updating data

### Contact

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**Other areas of specialty/work**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

There is no further information

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

